Acceptability of the Reality® Female Condom and a Latex Prototype

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ABSTRACT *We report on the comparative acceptability of a prototype latex female condom and the polyurethane Reality® female condom. We also identified factors associated with acceptability, measured via a composite index with domains related to ease of insertion, noise, and comfort during insertion and use. There were 135 couples in this randomized crossover trial. The average age was 30 years; more than 60% had education beyond high school; 40% were married; and participants were at low risk for sexually transmitted disease and pregnancy (due to the investigational status of the prototype). Participants were asked to use three of each of the study condoms during a 6-week period. Acceptability ratings on 12 items were summed into a composite index for each participant by condom type. The index midpoint (range) for females was 48 (12–84), and it was 32 (8–56) for males, with lower scores indicating higher acceptability (men completed only a subset of the acceptability questions). Both condoms were equally acceptable: Mean scores were 37 and 40 for the women's ranking of the prototype and Reality, respectively (P = .07) and 29 and 30 for men's rankings, respectively (P = .35). Multiple regression models to predict acceptability scores by gender were somewhat uninformative (most R^2 values were less than 0.10). Nevertheless, minority ethnicity (African American or Hispanic vs. white) was associated with higher acceptability by both genders for both condom types. Among women, for both condom types, less education (less than high school compared with high school or beyond) was associated with higher acceptability. Female condom acceptability may not be equally distributed across demographic groups, which is important for health educators to keep in mind when promoting the female condom.*

KEYWORDS *Acceptability, Barrier methods, Female condom, Prevention.*

INTRODUCTION

Women are at particularly high risk of sexually transmitted diseases (STDs), including the human immunodeficiency virus (HIV), due to issues of biological susceptibility, economic inequalities, and power imbalances between the genders.[1] The Reality® female condom is a barrier method designed to give women more control in protecting themselves from pregnancy and disease since it is used at the initiative of women. The US Food and Drug Administration (USFDA) approved the Reality female condom in 1993 for protection against pregnancy and STD/HIV. Unlike the majority of male condoms, Reality is made of polyurethane, a form of plastic. Acceptability studies of the device have shown that couples enjoy the heat-transmit-

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ting properties of polyurethane and report that sex with Reality feels natural.[2–4] However, polyurethane also makes the device expensive—up to 20 times the cost of a male condom. The current high price of Reality may contribute to women's reluctance to purchase, and donors' lack of enthusiasm to provide, the device throughout the developing world where HIV/AIDS (acquired immunodeficiency syndrome) is endemic. New barrier methods that capitalize on the female-initiated strengths of Reality but are more price competitive have the potential to increase the range of barrier methods available for women and may improve the demand for, and acceptance of, these products.

The Reddy female condom (manufactured by Medtech Products, Ltd., Chennai, India) is a prototype female condom made of latex and therefore will be significantly less expensive than Reality, the only marketed product. The Reddy female condom has not been approved for use by the USFDA or any foreign regulatory agency. It is classified as an investigational device and is not sold commercially. The device is a latex pouch with a V-shaped plastic stiffener attached to the rim of its open end. Similar to the outer ring of Reality, the stiffener remains outside the body during intercourse and covers the external genitalia. A polyurethane sponge is located at the closed end of the device and is meant to anchor the device during intercourse. The device is packaged with the sheath rolled up similar to a male condom and is prelubricated with silicone. It is inserted by pushing the sponge into the vagina. This action causes the sheath to unroll and extend to the end of the vaginal cavity.

Data for this article are from two randomized crossover trials with the primary objective of testing the slippage and breakage rates of the latex prototype. Results from these studies have been previously reported.[5] This article has the following separate aims. First, we report on the use and acceptability of the latex prototype compared with the polyurethane Reality female condom so that, if possible, design changes can be made to improve the performance of the latex prototype. Second, we identify factors associated with female condom acceptability.

METHODS

We conducted two randomized crossover trials using the same study protocol to evaluate the acceptability of a latex prototype female condom and the currently marketed Reality female condom. Results from the first trial led to three minor changes to the latex prototype. These modifications included attaching the outer stiffening rim more securely to the latex sheath, stamping the word "top" on the top of the outer ring to assist with proper orientation of the device during insertion, and shortening the sheath by 8 mm. The second study was conducted using the same protocol and the slightly modified latex prototype. These two studies provide information on the acceptability of both the existing and the prototype female condom.

Study Subjects
For the first study, couples were enrolled in equal proportions at two sites: a primary health care facility located in the Bronx, New York City, and the general population of Norfolk, Virginia. In the second study, subjects were recruited from a family planning clinic in Los Angeles, California, or from the general population via advertisements. Both studies assembled a convenience sample of volunteers, and participants were eligible to participate if they were in a monogamous, heterosexual

relationship; protected against pregnancy through use of hormonal or surgical contraceptive methods; not pregnant or seeking a pregnancy; not known to have sensitivities or allergies to polyurethane, latex, or vaginal lubricants; and reported low-risk HIV-related behaviors in the past 10 years. These criteria were needed because of the investigational status of the prototype. Participants also had to report no prior use of the Reality female condom. Both members of the couple had to be at least 21 years of age in the first study and 18 years old in the second. Both studies were approved by the institutional review boards of Family Health International (FHI) and of the institutions responsible for conducting these studies.

We used a prospective crossover design with simple randomization to condom use sequence. Randomization codes were generated at FHI using a computer program to determine the condom use sequence for a given couple. At study outset, codes were sent to each recruitment site in sealed, opaque envelopes that were sequentially numbered. After obtaining written informed consent, eligible participants completed a brief baseline questionnaire about their demographic characteristics and prior use of barrier methods. Participants were then randomly assigned to one of two condom use sequences: use of the Reality female condom followed by the latex prototype or the opposite order. Couples were assigned to a condom use sequence only after they were deemed eligible and had given informed consent.

Participants were then provided with a study packet that contained the manufacturer's instructions, three condoms, water-based lubricant, three condom use questionnaires, and an acceptability questionnaire for each member of the couple. Study staff provided instruction in the use of the condoms and asked participants to read the manufacturer's instructions before using the condoms. Couples were also instructed in how to complete the questionnaires and were asked to fill out one condom use questionnaire after each condom use. After using all three condoms, each member of the couple was instructed to fill out their respective acceptability questionnaires. Once the first set of condoms had been used, participants returned their questionnaires and were given their second study packet, which was identical to the first except for condom type. To minimize confusion in reporting, participants received their second study packet only after they had returned all questionnaires related to the first assigned condom. Couples were given a small stipend to reimburse them for their time and effort for the study.

Data Collection

Similar data collection instruments were used for each condom use sequence and for both studies. The condom use questionnaire measured the extent to which, and how, the condoms were used since lack of use could bias acceptability findings. The condom use questionnaires included detailed questions about insertion, lubrication, position and length of sexual intercourse, and performance of the condom during sex.[5] We report only details of insertion as these findings have implications for health education. The acceptability questionnaires asked participants to rate the condom using a 7-point Likert scale on 18 items related to ease and comfort during insertion, use and removal, appearance, fit, feel, lubrication, and the occurrence of noise. The acceptability measures, while not tested for reliability, were drawn from other published work to allow for comparability with other studies.[6] After using both condom types, couples were asked to compare each female condom under study with male condoms used in the past. They were asked about their confidence in the method, whether they would recommend each condom type to a friend,

whether they would purchase each condom type for their own use, and which condom they preferred (Reality or the latex prototype).

Statistical Analysis

All analyses conducted for this article were restricted to couples who used at least one of each condom type (n = 121 couples). We used SPSS version 10.0 (SPSS, Inc., Chicago, IL) for all data analysis. For each of the questions on how and when the condoms were inserted, we report proportions based on the total number of condoms inserted. Reponses on individual items measuring acceptability were not normally distributed; therefore, we report median item score by condom type. To reduce type I errors, we did not perform statistical testing on items that made up the index and instead reserved statistical testing for scores on the overall index, the main aim of this report. To evaluate propensity to purchase or recommend the condoms under study, we used the McNemar test within gender to compare across condom types and within a couple to compare a given condom type. We used the Wilcoxon signed rank test to evaluate within-gender responses to the question that asked participants to compare confidence in each device against the male condom. We considered P values less than .05 to be of importance.

To create an acceptability index, ratings of individual items were summed for each condom type, thereby weighting each item equally. The acceptability index was calculated separately for women and men since not all participants were involved with reading the instructions or inserting and removing the devices. The index for women was composed of 12 items, with item scores progressively ranging from most to least favorable. The women's scale had a possible range of 12 to 84, with lower scores representing a more favorable view and with the midpoint, 48, representing a neutral response. The index for men was composed of eight items; possible scores ranged from 8 to 56, and a score of 32 was neutral. We used one-sample t tests to compare each mean score against the neutral value on the acceptability scale and paired-sample t tests to compare mean scores for condom type within gender.

To identify factors associated with acceptability, we first calculated mean acceptability scores, by gender and condom type, for all categorical demographic and method use variables, and we calculated correlation coefficients for continuous variables. Since we had no a priori hypothesis about how characteristics might relate to the outcome, we built four linear regression models (one for each condom type by gender) using a backward elimination algorithm and $P < .10$ as the elimination criterion. Demographic and method use history was correlated within a couple. Therefore, each of these four modes was built with demographic and method use history data from either the male or female partner (eight models total). Variables entered in the full models were ethnic identity (African American and Hispanic vs. white as referent), education (beyond high school vs. high school or less as referent), relationship to partner (not living together vs. married as referent), number of years with partner, age in years, and prior use of the male condom or diaphragm (yes vs. no as referent).

RESULTS

A total of 135 couples (n = 270 individuals) were enrolled (70 couples in the first study and 65 in the second). Of the couples enrolled, 90% (121/135) had used at

least one of each condom type and are included in this analysis. There were no significant demographic differences between those included and excluded from this analysis at $P < .05$ (data not shown). Baseline characteristics of the study population are provided in Table 1. Despite eligibility criteria, one woman reported prior female condom use at baseline, but was retained in the analysis. Condom use and acceptability responses from the two studies were similar; therefore, data were pooled for analysis. Regarding condom insertion, 67% of the condoms were inserted by the female partner, 16% by the male partner, and 17% by both partners. Most participants (90%) reported inserting the device an hour or less before intercourse, 6% reported inserting the condom after intercourse began, while 2% reported inserting the condom more than 1 hour before intercourse (data not shown in tables).

Acceptability

Median scores from individual items measuring acceptability of each condom type are presented in Table 2. All items were rated as neutral or toward favorable. Women's ratings of the two devices were similar, but their ratings diverged on comfort during insertion and use, feel of lubrication during insertion, noise, and ease of removal. Men rated the two condoms similarly on individual attributes. Women and men both noted that the condoms produced little or no noise during use.

When asked directly about overall preference, propensity to purchase and recommend the devices, and confidence in the devices compared to male condoms, no

TABLE 1.   Baseline demographic characteristics and barrier method history

	Women (N = 135)	Men (N = 135)
Age, mean years (range)	30 (18–52)	31 (19–63)
Education, % (n)*		
≤ 12 years completed	27 (37)	39 (53)
> 12 years completed	73 (98)	59 (80)
Race/ethnicity, % (n)		
Asian	4 (6)	3 (4)
White, not Hispanic	46 (62)	47 (64)
Hispanic	29 (39)	25 (34)
African American	14 (19)	19 (25)
Other	7 (9)	6 (8)
Length of current relationship, mean years (range)	6 (0–30)	
Relationship with current partner, % (n)		
Married	39 (53)	
Not married, living together	37 (50)	
Not married, not living together	24 (32)	
Previous method use, % (n)†		
Male latex condom	90 (121)	97 (131)
Diaphragm	21 (29)	21 (29)

*Educational data missing for two male participants.
†Data on previous method used missing from one female participant.

TABLE 2. Median scores on acceptability scale items by gender for each condom type

	Women		Men	
	Latex prototype	Reality	Latex prototype	Reality
1. Ease of following manufacturer's instructions (1 = very easy, 7 = very difficult)	2	2	—	—
2. Ease of inserting condom* (1 = very easy, 7 = very difficult)	3	3	—	—
3. Comfort during insertion of condom* (1 = very comfortable, 7 = very uncomfortable)	3	4	—	—
4. Feel of lubricant† on condom during insertion* (1 = very pleasant, 7 = very unpleasant)	2	3	—	—
5. Amount of lubricant† on condom during insertion (1 = too much, 7 = too little)	4	4	—	—
6. General appearance of condom after insertion* (1 = very good, 7 = very poor)	4	4	4	4
7. General fit of condom* (1 = very good, 7 = very poor)	4	4	4	4
8. Length of condom (1 = very long, 7 = too short)	4	4	4	4
9. Width of condom (1 = too wide, 7 = too narrow)	4	4	4	4
10. Feel of condom material* (1 = very comfortable, 7 = very uncomfortable)	3	3	4	4
11. Smell of condom* (1 = very pleasant, 7 = very unpleasant)	4	4	4	4
12. Comfort during use* (1 = very comfortable, 7 = very uncomfortable)	3	4	4	4
13. Sensation of coolness or warmth during use (1 = cool, 7 = warm)	4	4	4	4
14. Sensitivity/stimulation during use* (1 = very good, 7 = very poor)	4	4	4	4
15. Noise during use* (1 = no noise, 7 = very noisy)	1	2	2	2
16. Feel of lubricant† on condom during use* (1 = very pleasant, 7 = very unpleasant)	3	3	3	3.5‡
17. Amount of lubricant† on condom during use (1 = too much, 7 = too little)	4	4	4	4
18. Ease of removing condom* (1 = very easy, 7 = very difficult)	2	1	—	—

*Denotes items included in the acceptability scale since these items were progressively ranked from most to least acceptable.

†Lubrication on condom as packaged.

‡Two modes existed, and the median fell between them.

definitive preference emerged (Table 3). Roughly half of the participants preferred the latex prototype, and half preferred the Reality female condom. About one third of participants (31%–37%) said they would be willing to purchase the female condoms under study, and 40%–47% said they would recommend the study condoms to a friend. Compared with male condoms used before the study, men reported

TABLE 3. Overall condom preferences and willingness to purchase or recommend each condom type

	Women		Men	
	Latex prototype, % (n)	Reality, % (n)	Latex prototype, % (n)	Reality, % (n)
Overall stated preference*	45 (54/119)	55 (65/119)	55 (66/119)	45 (53/119)
If needed to purchase a condom would buy the study condom†	37 (44/120)	39 (47/121)	31 (38/121)	31 (38/121)
Would recommend the study condom to a friend†	47 (56/120)	47 (57/121)	40 (48/121)	42 (51/121)
Confidence in study condom to protect from sexually transmitted disease and pregnancy compared with male condoms used before‡				
More/somewhat more confident	28 (30/106)	29 (31/108)	21§ (25/117)	28§ (32/116)
About the same amount of confidence	38 (40/106)	46 (50/108)	45 (53/117)	55 (64/116)
Less/somewhat less confident	34 (36/106)	25 (27/108)	33 (39/117)	17 (20/116)

Only *P* values less than .05 noted.

*Data missing from two couples.

†McNemar test performed for tests between condom types within gender for a given condom type. Data missing for one woman.

‡Wilcoxon signed ranks test performed for tests between condom types within gender and within couple for a given condom type. Denominators vary because not all participants had used a male condom prior to the study.

§*P* < .01 for a difference between condom types among males.

more confidence in the Reality condom than the latex prototype in the ability of the Reality condom to protect against pregnancy and STD.

Mean scores on the acceptability index for each condom type, by gender, are shown in Table 4. Overall, mean scores for each condom type for both genders were lower (toward favorable) than the neutral scale midpoint ($P < .001$ for all four comparisons). There was no difference in mean acceptability scores between condom types among women ($P = .07$) or among men ($P = .35$).

Predictors of Acceptability

Only one model held promise, with an adjusted R^2 of 0.17. This model was for women's acceptability scores on the latex prototype; they showed an inverse association between educational level and acceptability (Table 5). All other models explained less than 10% of the variance. Nevertheless, educational level was inversely associated with acceptability for the Reality condom, and ethnicity emerged as a consistent predictor of acceptability scores across gender and condom types. In all cases, African American or Hispanic ethnicity was associated with higher acceptability (i.e., lower scale score) compared to white ethnicity.

TABLE 4. Acceptability index scores by demographics, relationship types, and prior use of barrier methods

	Women		Men	
	Latex prototype	Reality	Latex prototype	Reality
Scale midpoint (scale range)*	48 (12–84)	48 (12–84)	32 (8–56)	32 (8–56)
Score mean (range) SD	37† (12–63) 11.6	40† (12–72) 13.5	29† (8–50) 9.0	30† (8–49) 9.0
Female ethnic identity, mean				
Asian	44	35	30	30
White	40	44	31	32
Hispanic	35	37	26	27
African American	31	33	27	26
Other	37	39	29	29
Male ethnic identity, mean				
Asian	44	37	30	28
White	40	42	30	32
Hispanic	37	38	26	27
African American	33	37	28	27
Other	35	41	33	31
Female education, mean				
≤High school	34	34	27	28
> High school	39	42	30	30
Male education, mean				
≤High school	31	38	27	29
>High school	41	41	30	30
Relationship to partner, mean				
Married	38	42	30	31
Not married, living together	36	39	28	29
Not living together	39	37	29	28
No. years with partner, correlation coefficient	0.12	0.11	0.03	0.06
Age of female partner, correlation coefficient	0.02	−0.00	−0.03	−0.08
Age of male partner, correlation coefficient	−0.07	−0.12	−0.15	−0.15
Female had used male condom before study, mean				
Yes	37	40	29	29
No	37	36	28	29
Female had used diaphragm before study, mean				
Yes	40	38	30	30
No	37	40	29	30

TABLE 4. Continued

	Women		Men	
	Latex prototype	Reality	Latex prototype	Reality
Male had used male condom before study, mean				
Yes	37	40	29	30
No	43	45	32	28
Male had been with diaphragm user before study, mean				
Yes	38	39	29	30
No	37	40	29	30

SD, standard deviation.

*Lower score indicates higher acceptability.

†Observed mean scores rated by men and women for each condom type were significantly different from scale midpoint using one-sample t tests, $P < .001$. Within gender, paired-sample t test comparing mean scores on each condom type within gender were $P = .07$ among women and $P = .35$ among men.

DISCUSSION

The main finding of this study is that both condom types were found to be acceptable and to be acceptable to the same degree. When individual aspects were summed into an index, overall scores for both condom types were significantly more favorable than the neutral midpoint. Women and men were largely similar in their rankings of the two condom types, but the women's ranking diverged on the topic of insertion. This finding parallels studies in the literature on the male condom, which have found that women are often more concerned about ease of condom use than its interference with sexual pleasure.[7] While reports of the Reality condom being difficult to insert are not new, literature studies suggest that ease of insertion improves with practice, even in as few as five uses.[8] The fact that we selected couples who had not previously used the Reality female condom and asked them to use only three devices also may have increased their challenges with insertion. Participants also reported little or no noise associated with use of the study condoms, which is striking because these empirical findings contradict the common perception that the female condom is noisy.[9]

Findings about how and when the condoms were inserted are also of interest. Men were involved with inserting the condoms about one third of the time. This suggests that men, as well as women, should be included in health education intervention on how to use the female condom. We also note that very few women took advantage of the fact that female condoms can be inserted far in advance of intercourse. This may be due to the stable nature of these participants' unions, as most were either married or living together; because the condoms were being used as part of a research study and not for protection; or because this practice is truly uncommon.

Our study population was assembled to test the breakage and slippage rates of the latex prototype; therefore, our measures were not specifically designed for this analysis. In fact, all but one of our models explained less than 10% of the variance in the acceptability score. Nevertheless, a lower educational level (less than high

school) predicted female condom acceptability of the latex prototype. Also, compared with white participants, acceptability scores for both female condom types were consistently higher for African American and Hispanic participants. The associations with ethnicity may not be due to participants' ethnic background per se; instead, ethnicity may have been a marker for participants' perceived STD risk. Nevertheless, this finding suggests that condom preference may not be equally distributed across demographic or risk groups and is an important point for health educators to keep in mind when promoting the female condom.

The concept of "acceptability" is often used in contraceptive research; yet, there is no standard definition. Female condom acceptability has been measured in a variety of populations and on multiple dimensions, including user likes and dislikes,[3] preferences regarding attributes,[6] qualitative aspects related to control and safety,[2,4,10] and actual use of the device.[11-13] Assuming that use of a female condom approximates acceptability, our search for factors associated with acceptability—even in this exploratory analysis—is partially consistent with the literature. Our findings are consistent with a study with longer follow-up in which female condom use was most likely to occur among minority couples.[13] Studies in the literature also suggest that female condoms tend to be used among younger people[14,15] and in steady partnerships among those with high-risk profiles.[10,11,13] The fact that our findings diverged at times from the published literature studies could be due to the limited variation in our study population with regard to these characteristics.

A major strength of this study was the randomized crossover design, which eliminated any possible bias in acceptability caused by an order effect. We also minimized reporting confusion since couples completed and returned all paperwork related to the first assigned condom before receiving the second. A unique contribution of this study was the benefit of being able to compare the Reality condom with another relatively novel barrier method, which avoids bias stemming from practice effect and familiarity.

Limitations of this study include generalizability, the post hoc nature of the analysis, and the fact that we could not verify that responses were based on actual condom use. Our findings should be considered exploratory since the study was not designed, or necessarily powered, to address the specific questions investigated in this report. Nevertheless, the findings suggest potential design improvements for the female condom and lend support to some of the literature profiling likely female condom users. Regarding the third limitation, we feel confident that the majority of couples adhered to the protocol given the consistency of their self-reports and their comments about how the condoms were used.

This study provided some insight into how female condoms are used and the kinds of people more likely to find them acceptable. Continued health education concerning the female condom should target both women and men at high risk for unwanted pregnancy, STDs, and HIV.

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TABLE 5. Regression models* for associations with female condom acceptability scores

		Acceptability rated by women				Acceptability rated by men			
		Latex prototype		Reality		Latex prototype		Reality	
	Adjusted R^2	Coefficient	P	Coefficient	P	Coefficient	P	Coefficient	P
Demographic and method use history reported by females	0.09								
Constant		35.1							
Ethnicity, African American/Hispanic vs. white (reference)		−5.0	.02						
Education >HS vs. ≤HS (reference)		4.8	.06						
Used diaphragm before study, yes vs. no (reference)		5.2	.05						
Demographic and method use history reported by males	0.17								
Constant		31.3							
Education, >high school vs. ≤high school (reference)		9.9	<.001						
Demographic and method use history reported by females	0.07								
Constant				37.6					
Ethnicity, African American/Hispanic vs. white (reference)				−5.1	.05				
Education, >high school vs. ≤high school (reference)				5.6	.05				

Demographic and method use history reported by males	0.05						
Constant		48.2					
Age, years		−0.4	.03				
Time with partner, years		0.6	.03				
Demographic and method use history reported by females	0.07						
Constant				31.8			
Ethnicity, African American/Hispanic vs. white (reference)				−5.0	.003		
Demographic and method use history reported by males	0.05						
Constant				31.6			
Ethnicity, African American/Hispanic vs. white (reference)				−4.2	.01		
Demographic and method use history reported by females							
Constant	0.07						
Ethnicity, African American/Hispanic vs. white (reference)						31.8	
Demographic and method use history reported by males						−5.0	.003
Constant	0.05					31.6	
Ethnicity, African American/Hispanic vs. white (reference)						−4.2	.01

*Backward elimination algorithm used with elimination criterion set at $P < .10$. Variables entered in all models included relationship characteristics and the demographic and method use history reported by either the female or the male partner; within-couple information was correlated and therefore could not be entered into the model simultaneously.

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